

Devine's PER-FO * * * Directions: * * * Contains: Alkaline Borate of Soda, Sodium Tripolx Phosphate, Sodium Sesquicarbonate, Sodium Alkyl Aryl Sulfonate, Natural Pine Needle Oil U.S.P. 3¼ Ozs. Weight Devines Remedies, Inc."; (btl.) "Devine's Zina-Ray Oil * * * Contains—Eucalyptus Oil, Menthol, Pine Needle Oil and Peppermint Oil. * * * Devine's Remedies"; and (envelope) "Devine's KARBO-Silekon Direction * * * Devine's Karbo Silekon is a combination of carbon and silicon baked on a waterproof material. * * * Devine's Remedies, Inc."

ACCOMPANYING LABELING: Leaflets entitled "Feet Hurt Burn . . . Tired . . . Itch . . . Ache????? Then use Devine's Kool-Foot For One Minute . . ."

RESULTS OF INVESTIGATION: Examination showed that the "inhaler" consisted of a round glass vial approximately 2½" long and ½" in diameter, with small openings at both ends and containing a small amount of absorbent cotton.

LIBELED: 2-9-61, E. Dist. Pa.

CHARGE: *Kool-Foot*, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for athlete's foot.

Ten Second Rub, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for headache, colds, and cough.

502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended, namely, (*Kool-Foot*) for preventing or treating foot trouble; (*Per-Fo* and *Improved Per-Fo*) for helping blood circulation and for treating foot trouble; (*Zina-Ray Oil*) for treating colds, preventing grippe, pneumonia, and flu, and for treatment of colds, coughs, sneezing, headache, and sinus trouble; (*Ten Second Rub*) for treatment of asthma, rheumatism, arthritis, sinus trouble, lumbago, sciatica, catarrh, headache, poor circulation, stiff joints, stiff necks, backache, leg cramps, croup, cough, and chest colds; and (*Karbo-Silekon*) for permanently removing corns and callouses, which were the conditions and purposes for which the articles were offered and recommended orally by Eleanor Callet, demonstrator, during the course of a lecture, on 11-30-60, at W. T. Grant Store, 11th and Market Street, Philadelphia, Pa.

DISPOSITION: 2-7-62. Default—destruction.

6923. Blood and nerve tonic, cough syrup, and liver-kidney regulator. (F.D.C. No. 46906. S. Nos. 25-141/3 T.)

QUANTITY: 32 16-oz. btls. of *blood and nerve tonic*, 115 4-oz. btls. of *cough syrup*, and 82 6-oz. btls. of *liver-kidney regulator*, at Benton Harbor, Mich.

SHIPPED: 10-15-61, from Gary, Ind., by Red Mountain Medical Co.

LABEL IN PART: (Btl.) "Red Mountain Blood and Nerve Tonic"; "The Famous Red Mountain Cough Syrup"; "Red Mountain Liver-Kidney Regulator"; (each btl. also labeled) "Mfd. by Red Mountain Medical Co. Dr. B. J. Cockrell Mfg. Chemist."

LIBELED: 1-8-62, W. Dist. Mich.

CHARGE: (*Blood and nerve tonic*), 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for promoting pep, vigor, and energy, for rundown nerves, impure blood, rheumatism, anemia, bladder weakness, swelling and stiffness of lower limbs and joints, skin diseases, and loss of appetite; and the

labeling contained false and misleading representations that another drug, *Red Mountain Liver-Kidney Regulator*, was adequate and effective as a treatment for biliousness, poor digestion, acid stomach, colds, kidney and back troubles, and general elimination of body waste and poisons; 502(b) (1)—the label failed to bear the name of the place of business of the manufacturer; and 502(f) (2)—the label listed potassium iodide as an active ingredient and failed to bear the warning statement required for oral preparations containing iodides, "If a skin rash appears, discontinue use and consult physician"; (*cough syrup*), 502(a)—the label contained false and misleading representations that the article was an adequate and effective treatment for coughs (unqualified), colds (unqualified and most severe), bronchial irritations, tight stuffy chest due to colds and exposure, and hoarseness; and the label contained false and misleading representations with reference to another drug, *Red Mountain Liver and Kidney Regulator Laxative*, that the use of the two drugs was adequate and effective as a treatment for deeply seated colds; (*liver-kidney regulator*), 502(a)—the label contained false and misleading representations that the article was an adequate and effective treatment for eliminating wastes and poisons from the system, relief of sluggish liver and kidneys, backaches, headaches, colds, constipation (unqualified), indigestion, gastric stomach, dizziness, high blood pressure, bad breath, no pep due to a bilious system, and to prevent serious menstrual pain; and the label contained false and misleading representations that another drug, *Red Mountain Blood and Nerve Tonic* was an adequate and effective treatment for the suffering of nervousness, rheumatism, impure blood, general rundown condition, and for toning and pepping up the system; and the label paragraph "General Directions" contained a statement which directed use of the product continuously, "2 to 3 times per week," which statement was false and misleading since it was contrary to the label warning statement "Caution: Frequent usage may result in laxative dependency"; and 502(f) (2)—the label declared the presence of the active laxative ingredient, phenolphthalein, and its label failed to bear the required phenolphthalein warning statement, "Caution: If skin rash appears do not use this or any other preparation containing phenolphthalein."

DISPOSITION: 2-12-62. Default—destruction.

6924. **E-Hi capsules and Isomar tablets.** (F.D.C. No. 45663. S. Nos. 19-982 R, 36-731 R.)

INFORMATION FILED: 12-19-61, S. Dist. Calif., against McCollum Laboratories, Inc., North Hollywood, Calif., Edward McCollum, president, and Florence McCollum, secretary-treasurer.

SHIPPED: 3-3-60 and 4-15-60, from California to Pennsylvania and Ohio.

LABEL IN PART: (Ctn.) "McCollum E-Hi Capsules * * * High Potency Source of Vitamin E * * * Made from Natural Vegetable Oils" and "Isomar * * * 150 Tablets * * * Distributed by McCollum Laboratories, Inc. Hollywood 28, Calif."

CHARGE: 502(f) (1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the articles were intended, namely (*Isomar tablets*), for the treatment and prevention of tiredness, indolence, cold hands and feet, loss of agility of mind, and sluggish memory; to build blood, and to keep blood in first class condition; and to produce vitality, warmth, proper tissue tone, and strength; and (*E-Hi capsules*), for the treatment and prevention of coronary heart